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Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office		SERIAL NO. 09/788,948
	N DISCLOSURE STATEMENT	APPLICANT Burch	
(Use sev	eral sheets if necessary)	FILING DATE 20 February 2001	GROUP Unknown

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
N	4,525,352	6/25/85	Cole et al.			
	4,282,202	8/4/81	Dowrick	.\		
	4,301,149	11/17/81	Crowley	<u> </u>		
	4,441,609	4/10/84	Crowley			
	4,537,887	8/27/85	Rooke et al.			
	4,673,637	6/16/87	Hyman			
	5,733,577	3/31/98	Myers et al.	. \	<u> </u>	
	6,051,255	4/18/00	Conley et al.			
W.	6,077,536	6/20/00	Merrifield et al.		<u> - </u>	
No	5,962,022	10/5/99	Bolt et al.	\	1	

FOREIGN PATENT DOCUMENTS

	Document	Date	Country	С	lass	Sub	class		slation
<u> </u>	Number	ļ				11		Yes	l No
LIV	WO 95/20946	8/10/95	WIPO			\prod			
P	WO 94/16696	8/4/94	WIPO			Ц			
	0 080 862	11/25/82	EPO						
	1 044 680 A1	10/18/00	EPO						
	2 005 538	4/25/79	Great Britain						
	WO 00/12088	3/9/00	WIPO						
	WO 91/15197	10/17/91	WIPO						
	WO 92/19227	11/12/92	WIPO	`					
	WO 93/00898	1/21/93	WIPO		,		$I \square$		
	WO 94/27557	12/8/94	WIPO						,
	WO 94/27600	12/8/94	WIPO						
	WO 95/28148	10/26/95	WIPO						
	WO 95/28927	11/2/95	WIPO						
	WO 96/04907	2/22/96	WIPO						
	WO 96/34605	11/7/96	WIPO						
	WO 97/09042	3/13/97	WIPO				Y		
1	WO 98/35672	8/20/98	WIPO						
M	WO 98/40054	9/17/98	WIPO						

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET NO. P50383D2	DIV. OF SERIAL NO. 09/788,948
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 NY	WO 98/42311	10/1/98	WIPO				Ш			
פע	EP 0281200A	2/26/88	EPC				Ц			
	EP 0389177A	3/15/90	EPC		1					
	HU 205611B	4/29/91	Hungary		7		\Box			
	WO 95/25516	9/28/95	WIPO		$oldsymbol{\perp}$					
-	WO 95/33487	12/14/95	WIPO						•	
	WO 96/04908	2/22/96	WIPO		,				<u></u>	
V_	WO 96/07408	3/14/96	WIPO			7.		\mathcal{L}		
-M	WO 00/03695	1/27/00	WIPO							
M	WO 98/07424	02/26/98	WIPO							

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Bottenfield et al., "Safety and Tolerability of a New Formulation...in the Empiric Treatment of Pediatric...Streptococcus pneumoniae", Pediatric Infect. Dis. J., Vol. 17, pp. 963-968 (1998) Arguedas et al., J. Antimicrob. Chemother., "In-vitro activity of cefprozil (BMY 28100) and loracarbef (LY 163892) against pathogens obtained from middle ear fluid", 27(3), 311-318, (1991) Legent et al., Chemotherapy(Based), "A Double-Blind Comparison of Ciprofloxacin and Amoxycillin/Clavulanic Acid in the Treatment of Chronic Sinusitis", 40(Suppl. 1), 8-15, (1994) Woodnutt et al, Antimicrobial Agents and Chemotherapy, "Efficacy of High-Dose Amoxicillin-Clavulanate against Experimental Respiratory Tract Infections Caused by Strains of Streptococcus pneumonia", 43(1), 35-40, (1999) Dagan et al., "Bacteriological and Clinical Efficacy of a New Amoxicillin/Clavulanate formulation (A/C-ES) in the Treatment of Acute Otitis Media (AOM), ABSTRACT Robinson, "Amoxicillin trihydrate/Clavulanic acid potassium salt", Med. Actual., 1982, 18(5) pgs Chan et al., "A comparative study of amoxicillin-clavulanate and amoxicillin. Treatment of otitis media with effusion." Archives of Otolaryngology - Head and Neck Surgery, Feb 1988, 114(2), pgs 142-146 Pichichero, "Resistant respiratory pathogens and extended-spectrum antibiotics", American Family Physican, 1995, 52(6), pgs 1739-1746 Hol et al., "Experimental evidence for Moraxella-induced penicillin neutralization in pneumococcal pneumonia", Journal of Infectious Diseases, 1994, 170(6), pgs 1613-1614 Baron et al., "Antimicrobial therapy in acute otitis media", Traitement Antibiotique de L'Otite Moyenne Aigue", Annales de Pediatrie, 1991, 38(8), pgs 549-555 Neville, "Augmentin: An in vitro study of bacterial sensitivities to a synergistic combination", New Zealand Medical Journal, 1982, 95(714), pgs 579-581 Pegler et al., "Augmentin treatment of bacterial infections in hospitalized patients", New Zealand Medical Journal, 1982, 95(713), pgs 542-545 Amendola et al., "Pediatric suspension of amoxycillin and clavulanic acid in the treatment of bacterial infections of the upper respiratory tract and ear", Minerva Pediatrica, 1989, vol. 41, no. 2, pgs. 97-103

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U.S. Department of Commerce Possible Patent and Trademark Office P50383D2

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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APPLICANT		
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FILING DATE	GROUP	
Herewith	Unknown	

NY	Astruc et al, "Efficacy and tolerance of a new formulation amoxicillin 100 mg – clavulanic acid 12.5 mg in acute otitis media in infants", Annales De Pediatrie, 1992, vol. 39, no. 2, 142-148
. 5	Aulton et al., "The Mechanical Properties of Hydroxypropylmethylcellulose Films Derived from Aqueous Systems", Drug Development and Industrial Pharmacy, 1981, 7(6), pgs. 649-668
	Beghi et al., "Efficacy and Tolerability of Azithromycin versus Amoxicillin/Clavulanic Acid in Acute
 	Purulent Exacerbation of Chronic Bronchitis", Journal of Chemotherapy, 1995, 7(2), pgs 146-152 Behre et al., "Efficacy of Twice-Daily Dosing of Amoxycillin/Clavulanate etc.", Infection, 3, pgs. 163-
	166
	Cook et al., "Efficacy of Twice-Daily Amoxycillin/Clavulanate etc.", BJC, 50(3), 1996, pgs. 125-128
	Cooper et al., "Effect of low concentrations of clavulanic acid on the in-vitro activity of amoxycillin against B-lactamase-producing Branhamella catarrhalis and Haemophilus influenzae", Journal of Antimicrobial Chemotherapy, 1990, vol. 26, pgs. 371-380
	Feldman et al., "Twice-daily antibiotics in the treatment of acute otitis media: trimethoprim-sulfamethoxazole versus amoxicillin-clavulanate", Can Med. Assoc. J., 1990, 142(2), pgs. 115-118
	Fink et al., "A trial of orally administered Augmentin in the treatment of urinary tract infection and lower respiratory tract infection in a children's hospital", Proc Eur Symp on Augmentin,
	Scheveningen June 1982, 1983: pgs 325-333 Fraschini et al., "Pharmacokinetics and Tissue Distribution of Amoxicillin plus Clavulanic Acid after Oral Administration in Man", Journal of Chemotherapy, 1990, 2(3), pgs 171-177
	Heikkinen et al., "Short-term use of amoxicillin-clavulanate during upper respiratory tract infection for prevention of acute otitis media", The Journal of Peds, Feb 1995, 126(2), pgs 313-316
	Hoberman et al., "Equivalent efficacy and reduced occurrence of diarrhea from a new formulation etc.", Journal of Pediatric Infect. Dis., 1997, 16, pgs. 463-470
	Hoberman et al., "Efficacy of amoxicillin/clavulanate for acute otitis media: relation to Streptococcus pneumoniae susceptibility", Pediatr Infect Dis Jr., 1996(15), pgs. 955-962
	Jacobsson et al., "Evaluation of Amoxicillin Clavulanate Twice Daily versus Thrice Daily in the Treatment of Otitis Media in Children", Eur. J. Clin. Microbiol. Infect. Dis., May 1993, pgs. 319-324
	Jeffries et al., "An Initial Assessment of Augmentin for the Treatment of Paediatric Infections in General Practice", The British Journal of Clinical Practice, 1996, pgs. 61-66
	Klein et al., "Antimicrobial Agents", Therapeutics - Part V, 1992, pgs. 2179-2198
	Kucer et al., "Ampicillin-like penicillins – Amoxycillin, Epicillin, Cyclacillin, Hetacillin, Pivampicillin, Talampicillin, Bacampicillin and Metampicillin", 2) "Clavulanic Acid", The Use of Antibiotics, 1987, pgs. 172-195/271-286
	Lachman et al., "Tablet Granulations", The Theory and Practice of Industrial Pharmacy, 1986, pgs. 314-320
	Lerk et al., "Interaction of lubricants and colloidal silica during mixing with excipients", Pharmacuetica Acta Helvetiae, 1997, 52(3) pgs 33-39
	Lieberman et al., "Pharmaceutical Dosage Forms – Tablets Second Edition, Revised and Expanded", 1989, vol. 2, pgs. 317-334
	McLaren et al., "A comparison of the efficacy and tolerability of Augmentin 625 mg po bd versus Augmentin 375 mg po tds in the tratment of acute bacterial exacerbations of chronic bronchitis", British Journal Clin Research, 1994 (5) pgs 1-10
	Neu, H. C., "Other B-Lactam Antibiotics", Principles and Practice of Infectious Diseases, 1990, pgs. 257-263
	Okhamapet et al., "Characterization of moisture interactions in some aqueous-based tablet film coating formulations", Journal Pharm Pharmacol, 1985(37), pgs 385-390
A	Parrott, "Densification of Powders by Concavo-Convex Roller Compactor", Journal of Pharm Sciences, March 1981, Vol 70(3), pgs 288-291
M	Ruberto et al., "Amoxycillin and Clavulanic Acid in the Treatment of Urinary Tract Infections in Children", Journal of International Medical Research, 1989, 17, pgs. 168-171.

Sheet 4 of 7

Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office		DIV. OF SERIAL NO. 09/788,948
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Burch	
(Use several sheets if necessary)	FIUNG DATE Herewith	GROUP Unknown

	V.	Saarnivaara et al., "Effect of Storage on the Properties of Acetylsalicylc Acid Tablets Coated with
	M	Aqueous Hydroxypropyl Methyl-Cellulose Dispersion", Drug Develop and Ind Pharmacy, 1985,
	101	11(2&3), pgs 481-492
	1	Sakellariou et al., "An evaluation of the interaction and plasticizing efficiency of the polyethylene
		glycols in ethyl cellulose and hydroxypropyl methylcellulose films using the torsional braid
	+-	pendulum", Int Journal of Pharm, 1986(31), pgs 55-64 Todd et al., "Amoxicillin/Clavulanic Acid´- An Update of its Antibacterial Activity, Pharmcokinetic
		Properties and Therapeutic Use", Drugs, 1990, 39(2), pgs 264-307
		Toh, "Amoxycillin with clavulanic acid", The Autstralian Nurses Journal, Dec/Jan 1995, Volume 18, No. 6, Abstract
		Tondachi et al., "Tablet Coating in an Aqueous System", Drug Develop and Ind Pharmacy, 1977, 3(3), pgs 227-240
		van Niekerk, "Pharmacokinetic Study of a Paediatric Formulation of Amoxycillin and Clavulanic Acid in Children", European Journal of Clinical Pharmacoloy, 1985, 29, pgs 235-239
1		Repertorio Farmaceutico Italiano, 3rd Edition 1989, A106 to A108. (Translation Included)
		Vidal 1994, 70th Edition, pgs. 132-134 (Translation Included)
		Prescribing for Children, British National Formulary, vol. 29, pg. 11
-+		Beta-Lactamase Inhibitors, The Pharmacological Basis of Therapeutics, eighth edition, pg. 1093
\rightarrow		Craig, et al., "Killing and Regrowth of Bacteria in Vitro: A Review", Scand J Infect Dis., 1991, Suppl
		74, pgs 63-70
,		Dagan, et al., "Bacteriologic and clinical efficacy of high dose amoxicillin/clavulanate in children
	<u> </u>	with acute otitis media", Pediatric Infectious Diseases Journal, 2001, vol 20, pgs 828-837
	\ ·	Lister et al., "Rationale behind High-Dose Amoxicillin Theraphy for Acute Otitis Media Due to
	١.	Penicillin-Nonsusceptible Pnsumococci: Support from In Vitro Pharmacodynamic Studies",
	+	Antimicrobial Agents and Chemotherapy, September 1997, vol 41, no 9, pgs 1926-1932 Woodnutt G. and Parker D.S. (1978) Rabbit liver acetyl-CoA synthetase. Biochem J. <u>175</u> , 757-759.
		Woodingt G. and Parker D.S. (1970) Rabbit liver acetyr-COA synthetase. Diochem J. 175, 757-759.
		Woodnutt G. and Parker D.S. (1979) Acetate entry rate into portal and peripheral blood in the rabbit. Proc. Nutr. Soc. 38, 724.
		Everett J.R., Jennings K.R., Woodnutt G. and Buckingham M.J. (1984) Spin echo NMR
		spectroscopy: A new method for studying penicillin metabolism. Chem Commun, 894-895.
		Everett J.R., Jennings K. and Woodnutt G. (1985) ¹⁹ F-NMR spectroscopy study of the metabolites of flucloxacillin in rat urine. J. Pharm. Pharmacol. <u>37</u> , 869-873.
		Woodnutt G. and Parker D.S. (1986) Acetate metabolism by tissues of the rabbit. Comp. Biochem. Physiol. 85B, 487-490.
		Woodnutt G., Kernutt I. and Mizen L. (1987) Pharmacokinetics and distribution of ticarcillin-
		clavualnic acid (Timentin) in experimental animals. Antimicrobial Agents and Chemotherapy <u>31,</u> 1826-1830.
		Woodnutt G., Catherall E.J., Kernutt I. and Mizen L. (1988) Temocillin efficacy in experimental
- [Klebsiella pneumoniae meningitis after infusion into rabbit plasma to simulate antibiotic
		concentrations in human serum. Antimicrobial Agents and Chemotherapy 32, 1705-1709
		Mizen L. and Woodnutt G. (1988) A critique of animal pharmacokinetics. Journal of Antimicrobial Chemotherapy <u>21</u> , 273-280.
		Woodnutt G., Kernutt I. and Mizen L. (1989) Penetration of Augmentin and Timentin into lymph
)	after simulation of human serum pharmacokinetics in the rabbit. J. Drug Devel. 2, Suppl. 1, 123-126.
W	N	Catherall E., Woodnutt G. and Mizen L. (1989) Distribution and efficacy studies with ticarcillin-
- /	$ \mathcal{U}_{k} $	clavulanic acid (Timentin) in experimental Klebsiella pneumoniae meningitis in rabbits. J. Drug
'	1 ~1	Devel. 2. Suppl. 1. 127-130.

Sheet <u>5 of 7</u>.

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY, DOCKET NO. P50383D2	DIV. OF SERIAL NO. 09/788,948
	ON DISCLOSURE STATEMENT BY APPLICANT	APPUCANT Burch	
(Use se	veral sheets if necessary)	FIUNG DATE Herewith	GROUP Unknown

M	Woodnutt G., Catherall E.J., Kernutt I. and Mizen L. (1989) Influence of simulated human
N N	pharmacokinetics on the efficacy of temocillin against a Klebsiella pneumoniae meningitis infection
N N	in the rabbit. J. Chemother., Suppl. 4, 475-476
W.	Mizen L., Woodnutt G., Kernutt I. and Catherall E. (1989) Simulation of human serum
	pharmacokinetics of ticarcillin-clavulanic acid and ceftazidime in rabbits, and efficacy against
	experimental Klebsiella pneumoniae meningitis. Antimicrobial Agents and Chemotherapy 33, 693-
	699.
	Everett J. R., Tyler J.W. and Woodnutt G. (1989) A study of flucloxacillin metabolites in rat urine by
	two-dimensional ¹ H, ¹⁹ F COSY NMR. Journal of Pharmaceutical and Biomedical Analysis, <u>7</u> , 397-
	403.
	Woodnutt G., Berry V., Kernutt I. and Mizen L. (1990) Penetration of amoxycillin, ticarcillin and
l i	clavulanic acid into lymph after intravenous infusion in rabbits to simulate human serum
	pharmacokinetics. Journal of Antimicobial Chemotherapy <u>26</u> , 695-704.
	Slocombe B., Brown T.N., Cooper C.E., Catherall E. and Woodnutt G. (1990) In vitro and in vivo
	activity of temocillin. Research and Clinical Forums 12, 21-33.
	Woodnutt G., Berry V. and Mizen L. (1992) Simulation of human serum pharmacokinetics of
	cefazolin, piperacillin, and BRL 42715 in rats and efficacy against experimental intraperitoneal
	infections. Antimicrobial Agents and Chemotherapy 36, 1427-1431.
	Connor S.C., Everett J.R., Jennings, K.R., Nicholson J.K. and Woodnutt G. (1994) High resolution
	¹ H NMR Spectroscopic studies of the metabolism and excretion of ampicillin in rats and
	amoxycillin in rats and man. J. Pharm. Pharmacol. 46, 128-134.
	Woodnutt G., Berry V., Bryant J. Gisby J. and Slocombe B. (1995) Efficite de l'association
	amoxicilline-acide clavulanique dans un modele d'abces sous-cutane a E. coli chez le rat apres
	simulation de l'administration chez l'homme de 1g/200mg (IVD) ou de 2g/200mg (perfusion). La
- 1	lettre de l'infectiologie de la microbiologie a la clinique. Numero hors-serie. 23-26.
	Burgess W.J., Bryant J. and Woodnutt G. (1995) Uptake of clavulanic acid across rat jejunal
	Burgess W.J., Bryant J. and Woodnutt G. (1995) Uptake of clavulanic acid across rat jejunal segments in vitro. J. Physiology, 482, 41P
	segments in vitro. J. Physiology, 482, 41P
	segments in vitro. J. Physiology, <u>482</u> , 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin
	segments in vitro. J. Physiology, <u>482</u> , 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy <u>39</u> , 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract
	segments in vitro. J. Physiology, <u>482</u> , 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy <u>39</u> , 1859-1861.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alpha-
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alphatoxin virulence in Stahylococcus aureus Infection. J. Bact. 181, 6585-6590. Hannan P. and Woodnutt G. (2000) In vitro activity of gemifloxacin (SB-265805; LB20304a)
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alphatoxin virulence in Stahylococcus aureus Infection. J. Bact. 181, 6585-6590. Hannan P. and Woodnutt G. (2000) In vitro activity of gemifloxacin (SB-265805; LB20304a) against human mycoplasmas. J. Antimicrob. Chemother. 45, 367-369.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alphatoxin virulence in Stahylococcus aureus Infection. J. Bact. 181, 6585-6590. Hannan P. and Woodnutt G. (2000) In vitro activity of gemifloxacin (SB-265805; LB20304a) against human mycoplasmas. J. Antimicrob. Chemother. 45, 367-369. Berry V., Page R., Satterfield J., Singley C., Straub R. and Woodnutt G. (2000) Comparative in
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alphatoxin virulence in Stahylococcus aureus Infection. J. Bact. 181, 6585-6590. Hannan P. and Woodnutt G. (2000) In vitro activity of gemifloxacin (SB-265805; LB20304a) against human mycoplasmas. J. Antimicrob. Chemother. 45, 367-369. Berry V., Page R., Satterfield J., Singley C., Straub R. and Woodnutt G. (2000) Comparative in vivo activity of gemifloxacin in a rat model of respiratory infection. J. Antimicrob. Chemother. 45,
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alphatoxin virulence in Stahylococcus aureus Infection. J. Bact. 181, 6585-6590. Hannan P. and Woodnutt G. (2000) In vitro activity of gemifloxacin (SB-265805; LB20304a) against human mycoplasmas. J. Antimicrob. Chemother. 45, 367-369. Berry V., Page R., Satterfield J., Singley C., Straub R. and Woodnutt G. (2000) Comparative in vivo activity of gemifloxacin in a rat model of respiratory infection. J. Antimicrob. Chemother. 45, Suppl. S1, 79-85.
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alphatoxin virulence in Stahylococcus aureus Infection. J. Bact. 181, 6585-6590. Hannan P. and Woodnutt G. (2000) In vitro activity of gemifloxacin (SB-265805; LB20304a) against human mycoplasmas. J. Antimicrob. Chemother. 45, 367-369. Berry V., Page R., Satterfield J., Singley C., Straub R. and Woodnutt G. (2000) Comparative in vivo activity of gemifloxacin in a rat model of respiratory infection. J. Antimicrob. Chemother. 45, Suppl. S1, 79-85. Berry V., Page R., Satterfield J., Singley C., Straub R. and Woodnutt G. (2000)
	segments in vitro. J. Physiology, 482, 41P Berry V., Jennings K. and Woodnutt G. (1995) Bactericidal and morphological effects of amoxicillin on Helicobacter pylori. Antimicrobial Agents and Chemotherapy 39, 1859-1861. Mizen, L., V. Berry and G. Woodnutt. (1995) The influence of uptake from the gastrointestinal tract and first pass effect on oral bioavailability of (Z) -alkyloxyimino penicillins. J. Pharm. Pharmacol. 47, 725-730. Woodnutt G., Berry V.J. and Mizen L.W. (1995) The effect of protein binding on the penetration of beta-lactams into rabbit peripheral lymph. Antimicrobial Agents and Chemotherapy 39, 2678-2683. Berry V., Thorburn C.E., Tyler J. and Woodnutt G. (1998) Bacteriological efficacy of three macrolides compared with amoxicillin/clavulanate against S. pneumoniae and H. influenzae. Antimicrobial Agents and Chemotherapy 42, 3193-3199. Woodnutt G. and Berry V. (1999) The use of two pharmacodynamic models to assess the efficacy of amoxicillin/clavulanate against experimental respiratory tract infections caused by strains fo S. pneumoniae. Antimicrobial Agents and Chemotherapy 43, 29-34. Ji Y., Marra A., Rosenberg M and Woodnutt G. (1999) Regulated antisense RNA eliminates alphatoxin virulence in Stahylococcus aureus Infection. J. Bact. 181, 6585-6590. Hannan P. and Woodnutt G. (2000) In vitro activity of gemifloxacin (SB-265805; LB20304a) against human mycoplasmas. J. Antimicrob. Chemother. 45, 367-369. Berry V., Page R., Satterfield J., Singley C., Straub R. and Woodnutt G. (2000) Comparative in vivo activity of gemifloxacin in a rat model of respiratory infection. J. Antimicrob. Chemother. 45, Suppl. S1, 79-85.

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	Manda H C (2000) Pharmand marries to Combat Resistance II Antimicash Chamathas 46
W	Woodnutt G. (2000) Pharmacodynamics to Combat Resistance. J. Antimicrob. Chemother. <u>46,</u> Suppl. T1, 25-31.
N	Brooks G., Burgess W., Colthurst D., Hinks J.D., Hunt E., Pearson M.J., Shea B., Takle A.K., Wilson J.M. and Woodnutt G. (2001) Pleuromutilins. Part 1: The identification of novel mutilin 14-carbamates. Bioorganic and Medicinal Chemistry 9, 1221-1231.
	Ji Y., Zhang B., Van Horn S.F., Warren P., Woodnutt G., Burnham M.K.R. and Rosenberg M. (2001) Identification of critical staphylococcal genes using conditional phenotypes generated by antisense RNA. Science 293, 2266-2269
	Barry et al., "Effect of Increased Dosages of Amoxycillin in Treatment of Experimental Middle Ear Otitis Due to Penicillin-Resistant Streptococcus pneumoniae", Antibacterial Agents and Chemotherapy, August 1993, Vol 37, No. 8, pgs. 1599-1603
	Craig, "Antimicrobial Resistant Issues of the Future", Diagn Microbiol Infect Dis, 1996, 25, pgs. 213-217
	Craig et al., "Pharmacokinetics and pharmacodynamics of antibiotics in otitis media", Pediatr Infections J, 1996, 15, pgs.255-259
	Finch, "Pneumonia: The Impact of Antibiotic Resistance on its Management", Microbial Drug Resistance, Vol 1, No. 2, 1995, pgs. 149-158
	Friedland et al., "Management of Infections caused by Antibiotic-Resistant Streptococcus Pneumoniae", The New England Journal of Medicine, 1994, Vol. 331, No. 6, pgs. 377-382
	McCracken, "Emergence of resistant Streptococcus pneumoniae: a problem in pediatrics", Pediatr Infect Dis J, 1995, 14, pgs. 424-428
	Pankuch et al., "Comparative activity of ampicillin, amoxycillin, amoxycillin/clavulanate and cefotaxime against 189 penicillin susceptible and -resistant pneumococci", Journal of Antimicrobial Chemotherapy, 1995, 35, 883-888
	Martindale, The Extra Pharmacopoeia, Thirtieth Edition, Edited by James E. F. Reynolds (London, The Pharmaceutical Press, 1993), pgs 115-116 and 148
	Merck Index 1989, 610 and 2342
	1996 MIMS Annual, Twentieth Edition, May 1995, pgs. 8-476 to 8-477
	Calver et al., "Dosing of Amoxicillin/Clavulanate Given Every 12 Hours Is as Effective as Dosing Every 8 Hours for Treatment of Lower Respiratory Tract Infection", Clinical Infectious Disease, 1997, 24, pgs 570-574
	Calver et al., "Augmentin Bid Versus Augmentin TID in the Treatment of Lower Respiratory Tract Infections", Can J. Infect Dis, 1995, Vol 6 Suppl C, Abstract no. 0338, pg 239C ABSTRACT
_	Calver et al., "Amoxicillin/Clavulanate BID vs A/C TID in the Treatment of Lower Respiratory Tract Infections", Abstracts of the 35th ICAAC, 1995, pg 334
	Moonsammy et al., "Improved Safety Profile of a New Amoxicillin/Clavulanate Adult BID Formulation Compared with the Standard A/C TID Formulation", Abstracts of the 36th ICAAC, 1996, pg 290
	Ball et al., "Clavulanic Acid and Amoxycillin: A Clinical, Bacteriological, and Pharmacological Study", The Lancet, March 22, 1980, Vol. I, Pgs 620-623
	Caron et al., "Effects of Amoxicillin-Clavulanate Combination on the Motility of the Small Intestine in Human Beings", Antimicrobial Agents and Chemotherapy, June 1991, Vol. 35 No. 6, pgs 1085-1088
\int	Crokaert et al., "Activities of Amoxicillin and Clavulanic Acid Combinations Against Urinary Tract Infections", Antimicrobial Agents and Chemotherapy, Aug 1982, Vol 22 No. 2, pgs 346-349
A'	Staniforth et al., "Effect of food on the bioavailability and tolerance of clavulanic acid/amoxycillin combination", Journal of Antimicrobial Chemotherapy, (1982)10, pgs 131-139
M	Stein et al., "Amoxicillin-potassium clavulanate, a B-lactamase-resistant antibiotic combination", Clinical Pharmacy, Vol. 3, Nov-Dec 1984 pgs 591-599

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(Use several sheets if necessary) Herewith	h Unknown

Flatulence, Diarrhoea, and Polyol Sweetners, The Lancet, December 3, 1983, Vol. II, pg 1321 Handbook of Pharmaceutical Excipients, Third Edition, Arthur H. Kibbe, Ph.D., pgs 324-328 The Use of Antibitiotics, 4th Edition, J. B. Lippincott Company, pgs 278-279 Therapeutic Drugs, Dollery, 1999, pgs C253-C256

DATE CONSIDERED
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